

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 520**

21113

Display Date	02-05-02
Publication Date	02-06-02
Certifier	A. Corbin

**Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The ANADA provides for a revised withdrawal time for use of oxytetracycline (OTC) hydrochloride (HCl) soluble powder in the drinking water of turkeys and swine.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed a supplement to ANADA 200-066 that provides for use of AGRIMYCIN 343 (oxytetracycline HCl) Soluble Powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for a zero-day withdrawal time after the use of the product in the drinking water of turkeys and swine. The supplemental application is approved as of October 4, 2001, and the regulations are amended in 21 CFR 520.1660d to reflect the approval.

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Section 520.1660d is also being amended to reflect approval of a 5-pound pail size, which was approved under ANADA 200–066 on June 15, 1994.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

#### **List of Subjects in 21 CFR Part 520**

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### **PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

2. Section 520.1660d is amended in paragraph (a)(6) by adding “; pail: 5 lb” after “oz.”; in paragraphs (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), and (d)(1)(ii)(C)(3) in the sixth sentence by removing “; 057561,” and in the eighth sentence by numerically adding “057561,”; and in paragraph (d)(1)(iii)(C) by revising the last sentence to read as follows:

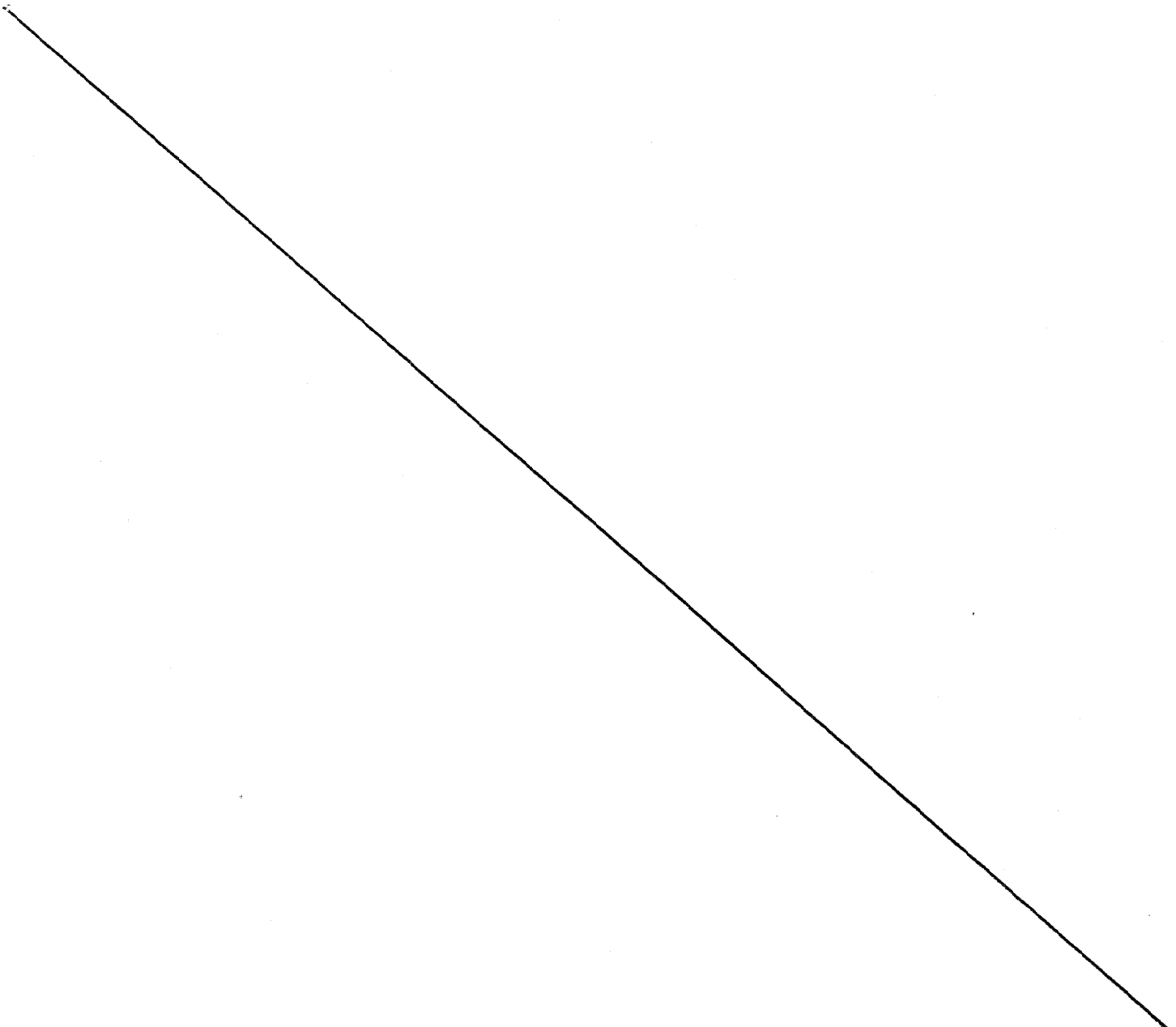
§ 520.1660d Oxytetracycline hydrochloride soluble powder.

\* \* \* \* \*

(d) \* \* \*

(l) \* \* \*

(iii) \* \* \*



(C) \* \* \* Administer up to 5 days; do not use for more than 5 consecutive days; withdraw  
zero days prior to slaughter those products sponsored by Nos. 046573, 057561, and 061133.

Dated: Jan 11, 2002

January 11, 2002.

1-31-02  
B Bodo  
per OFR

Claire M. Lathers

Claire M. Lathers,  
Director,  
Office of New Animal Drug Evaluation,  
Center for Veterinary Medicine,  
[FR Doc. 01-??-?? Filed ??-??-01; 8:45 am]

B Bodo 1-29-02

BILLING CODE 4160-01-S

